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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,697	01/03/2001	Charles W. Bishop	17620/9316	1609
23510	7590	06/18/2004	EXAMINER	
MICHAEL BEST & FRIEDRICH, LLP ONE SOUTH PINCKNEY STREET P O BOX 1806 MADISON, WI 53701				CRIARES, THEODORE J
ART UNIT		PAPER NUMBER		
		1617		

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/753,697	BISHOP ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Theodore J. Criares	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 February 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2-6,11,13-20,25 and 28-86 is/are pending in the application.
- 4a) Of the above claim(s) 15,16,18-20, 25 36 and 37 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 2-6,11,13,14,17,28-35 and 38-86 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____.   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/15/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____.                                   |

**CLAIMS 2-6, 11, 13-20, 25 AND 28-86 ARE**  
**PRESENTED FOR EXAMINATION**

Claims 15, 16, 18-20, 25, 36 and 37 are withdrawn from consideration as drawn to a non-elected invention.

The rejection under 35 USC 112, first paragraph is withdrawn in view of applicants' amendments to the claims.

The Obvious Double Patenting rejection is also withdrawn in view of applicants' persuasive arguments.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Regarding claims 2, 3, 13, the phrase "or equivalent" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or equivalent"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

**OBJECTION TO THE CLAIMS**

Claims 4, 38, 5, 28 and 31 are objected to because of the following informalities:

Claims 4, 28 and 38 fails to define (m)

Claim 5 reads on a subsequent numbered claim which is improper.

Claim 31 fails to exclude the parenthesis.

Appropriate correction is required.

## DETAILED ACTION

### DOUBLE PATENTING REJECTION

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-6, 11, 13, 14, 17, 28-35 and 38-86 are rejected under the judicially created doctrine of double patenting over claims 1-5 and 10-14 of U. S. Patent No. 6,242,434 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the claims in the subject application are generic to claims 1-5 and 10-14 of the patent. The difference between the patent claims and the claims in the application is the definition of R<sup>4</sup>. In the patent this radical is lower alkyl. In the application claims are drawn to a similar radical, e.g. claim 31. The claims in the patent could have been drawn to the method claims 2-6, 11, 13, 14, 17, 28-35 and 38-

86 of the present application since Examples 8-16 are similar in the patent and application.

This obvious type double Patenting rejection is deemed proper.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6, 11, 13, 14, 17, 28-35 and 38-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sestelo et al. (Re. 36,854).

Sestelo et al. at column 2, line 4 to column 3, line 11 teach the compounds within applicants claims for the treatment of osteoporosis, cancers, inflammation, etc. as set forth at column 2, lines 38-49. The difference between applicants' claimed compounds and the patent is that the Vitamin D compounds of the patent generically teaches a hydrogen or hydroxyl radical at the one (1) position. However, in the reference there is a failure to illustrate this compounds activity by examples. There is a teaching in the patent that the compound can be made as seen at column 4, line 50 to column 5, line

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17. The teachings in this reference clearly obviate applicants' claims since it teaches previtamin D compounds.

This reference also claims in claim 10 Vitamin D compounds within applicants' claims since in claim 1 of the reference R<sub>3</sub> is a hydroxyl group and R<sub>1</sub> is hydrogen.

The claims read on "a 24-hydroxy " Vitamin D compound as the active agent. These claims do not limit the active agents to only such agents, but includes all Vitamin D compounds having a hydroxyl group in the 24 position and hydrogen in the one (1) position.

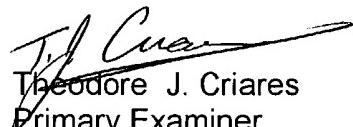
The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 18 USPQ 2d 1885, (Fed. Cir. 1991). In view of the above rejection it is deemed that the evidence presented has established a prima facie case of obviousness. is presented.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is (571) 272-0625. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Theodore J. Criares  
Primary Examiner  
Art Unit 1617

6/15/04  
tjc